

### Remarks

#### A. Status of Claims

Claims 17, 32-33, 73-74, and 80 were pending. Each claim has been canceled for clarity and to simplify the claim listing. Claims 81-100 have been added. No new matter has been added.

##### 1. Example Claim Support

Claims 81-100 are based closely on the claims that were previously pending in the application.

Support for new Claim 81 can be found in previous Claim 69. The claim has been further amended to specify that the medical or surgical fastener is sterile and therefore that the fastener comprises a “sterile tubular sleeve.” Support for this further amendment can be found in original Claim 43, which recites a “medical or surgical apparatus.” It is commonly known that medical and surgical apparatus should be sterilized before use; therefore, the tubular sleeve of the present fastener is sterilized in this claimed embodiment.

Support for new dependent Claims 82-91 can be found in previous Claims 70-79.

Support for new dependent Claim 92 can be found in previous Claim 80, but the term “collar” has been replaced by the term “ring” in this claim. The claim has also been further amended to specify that the ring is “operable to shorten the length of the sleeve.” Support for this amendment can be found in each of Figs. 9-15, for example Fig. 12 and the accompanying description on Page 16, Lines 19-26, which discloses that the tubular sleeve may be provided with “a ring at its free end.” Further support can be found on Page 17, Lines 17-19, which specify that “the rings are moveable in mutual alignment in a straight line towards and away from one another along the longitudinal axis of the tubular sleeve” and in Fig. 5(k). Therefore, the disclosed ring is operable to shorten the length of the sleeve.

Support for new Claim 93 can be found in previous Claim 80, which has been amended to specify that the sleeve is of a filamentary construction and that a collar is provided, which holds together the free ends of the filaments making up the sleeve. Support for this amendment can be found on Page 13 Lines 3-4.

New Claim 94 finds support in original Claim 38.

New independent Claim 95 finds support in previous Claim 69. The claim has been further amended to add that the tubular sleeve has a ring at at least one end, the ring surrounding the first aperture or the second aperture and the ring being operable to shorten the length of the sleeve. Support for this amendment can be found in each of Figs. 9-15, for example Fig. 12 and the accompanying description on Page 16, Lines 19-26, which discloses that the tubular sleeve may be provided with "a ring at its free end." Further support can be found on Page 17, Lines 17-19, which specify that "the rings are moveable in mutual alignment in a straight line towards and away from one another along the longitudinal axis of the tubular sleeve" and in Fig. 5(k). Therefore, the disclosed ring is operable to shorten the length of the sleeve.

Support for dependent Claims 96-99 can be found in previous Claims 73 and 76-78 respectively.

Support for new dependent Claim 100 can be found in Figs. 10a, 10b and 12, and Page 15, Lines 24-25.

B. Section 112

1. The Rejection of Claim 80 Is Overcome

Claim 80 was rejected under 35 U.S.C. § 112, first paragraph for allegedly lacking enablement. Claim 80 has been canceled, rendering this rejection moot. However, new Claims 92 and 93 are each based on previous Claim 80 and will be addressed with respect to this rejection.

New Claim 92 corresponds to previous Claim 80 but has been amended to replace the term "collar" with the term "ring." As noted above, support for the fastener comprising a ring can be found in each of Figs. 9-15. In describing Fig. 12, Page 16, Line 23 discloses that the sleeve has "a ring at its free end" which enables "the free end of the sleeve to be pulled manually away from the pad when it is desired to grip a line extending within the sleeve." Further, in describing Fig. 15, Page 17, Lines 14-15 disclose "a first ring supporting one end of a sleeve and a second ring supporting the other end of the sleeve;" Lines 17-19 further describe the rings being operable to shorten the length of the sleeve: "the rings are moveable in mutual alignment in a straight line towards and away from one another along the longitudinal axis of the tubular sleeve." Hence, new Claim 92 is fully enabled by the specification.

New Claim 93 discloses that the tubular sleeve is of filamentary construction and has a collar at at least one end of the sleeve, the collar holding together the free ends of the filaments making up the sleeve. As noted by the Examiner, this feature is enabled by the disclosure on Page 13, Lines 3-4. Hence, new Claim 93 is fully enabled by the specification.

The newly-presented claims are fully enabled by the specification, and the rejection to claim 80 is overcome.

C. Section 103

Claims 17, 32-33, 73-74, and 80 were rejected under 35 U.S.C. § 103 as allegedly being obvious in view of Shorey (GB 2,061,372). Claims 73-74 and 80 were rejected under 35 U.S.C. § 103 as allegedly being obvious in view Shorey combined with Gunnell (US 656,187). Each of these claims have been canceled, rendering the rejections moot. However, the newly-presented claims will be addressed with respect to these rejections.

Since the independent claims in the new listing of claims are based closely on previous Claim 69, Applicant will address the objections raised in the present Office Action and then will address the Examiner's objections to previous Claim 69 in the Office Action of 5 June 2006.

1. Claim 81 Is Not Obvious In View of Shorey and/or Gunnell

The non-obvious nature of Claim 81 will be discussed below with reference to factual inquiries stated in *Graham v. John Deere Co.* 383 U.S. 1, 148 USPQ 459 (1966), among other analysis.

a. *Determining the scope and content of the prior art*

The Examiner has rejected the previous claims of the application under 35 U.S.C. §103(a) as being unpatentable over Shorey et al. (GB 2,061,372).

b. *Differences between the claimed invention and the prior art*

As recognized by the Examiner, Shorey discloses a "cable grip" for fitting over a cable. Shorey does not disclose "a medical or surgical fastener." Indeed, Shorey does not teach or suggest the use of the cable grip described in any field other than hardware. Therefore, it is further clear that **Shorey nowhere discloses providing a "sterile tubular sleeve."** Hence, there is clearly a gap between the cited art and the claimed invention. Gunnell does not fill this gap, nor is the invention rendered obvious by any other means.

*c. Resolving the level of ordinary skill in the art*

Since the claimed fastener is a medical or surgical fastener, it is respectfully submitted that a person of ordinary skill in the pertinent art would have been a medical practitioner, such as a doctor. Such a person would have been aware of the previous mechanisms for securing a tube to a patient, such as the adhesive tape bridges and other devices disclosed on Pages 2-7 of the present application. Indeed, as noted in the present application, the inventor is himself a doctor and the introduction of the present application therefore sets out the prior art that a doctor (our person of ordinary skill in the pertinent art) was aware of at the time of the invention.

*d. Teaching / Suggestion / Motivation test*

The cited art does not teach, suggest, or motivate the present invention. Applicant is mindful that the teaching, suggestion, motivation test (TSM test) is not the only test for analyzing obviousness and that courts should apply the test flexibly; however, the TSM test remains “the primary guarantor” against hindsight analysis, which appears to be present in the current Office Action:

As this court has explained, however, a flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis such as occurred in this case. In re Translogic Tech., Inc., 504 F.3d 1249, 1257 (Fed. Cir. 2007) (“[A]s the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of invention.”). The TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence – teachings, suggestions (a tellingly broad term), or motivations (an equally broad term) – that arise before the time of invention as the statute requires.

*Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, No. 2007-1223, slip op. at 11 (Fed. Cir. Mar. 31, 2008).

It is clear from the discussion above that the provision of a medical or surgical fastener comprising a sterile tubular sleeve having the claimed construction is nowhere taught in the cited art. Therefore, it is simply **not possible** to combine elements from the cited documents, or to substitute one element with an element from another document to arrive at the claimed fastener.

The Applicant respectfully submits that the Examiner has erred in his finding that “it would have been obvious to one of ordinary skill in the art to recognize that the cable line and the tube are interchangeable and can be used in medical arts.” The Examiner’s assertion appears to be based on impermissible hindsight, given the lack of any teaching, suggestion, or motivation to arrive at the present invention.

In the absence of any teaching, suggestion or motivation, which has not been demonstrated by the Examiner, it would not be obvious for a person of ordinary skill in the medical field to look to the field of hardware (and, more particularly, to the field of cable grips for “a building or pole, down an excavation, in a mine shaft and elsewhere” as disclosed by Shorey at Page 1, Lines 26-29) to provide an improved medical device. Further, the cable grip described in Shorey is **not directly useable** as a medical or surgical fastener, since it does not provide a sterile tubular sleeve suitable for use in a medical setting. Therefore, simple application of the device of Shorey in the medical field as suggested by the Examiner would not bring the skilled person to the claimed invention. The cited art nowhere discloses providing a sterile tubular sleeve as a medical fastener. Therefore this missing feature could not be added based on the teaching of Gunnell or any of the other art of record.

*e. Further objective evidence of non-obviousness*

The validity of the Applicant's assertion that it was not obvious to use the claimed fastener in the medical field is supported by the objective evidence that there has clearly been a **long-felt need** in the medical community to find an improved mechanism for securing tubes to patients. This is evidenced by the many types of fastener that have been developed by the medical community over the years. Some of these types of fastener are described in Pages 2-7 of the present application. For example Page 3, Lines 1-13 disclose that medical adhesive tape was previously used to form a tape bridge. A more sophisticated version of the bridge is described in Conway (US 5,370,627) referenced on Page 4 Lines 12-16. Foshee (US 5,257,975), described on Page 6 Lines 16-25 discloses an alternative approach to the line-fixing problem, but this requires modification of the article being attached to the patient. Hence, over many years of medical practice, **the problem of securing a tube to a patient is one that has never been satisfactorily solved.**

It is further noted that cable grips for use in the field of hardware, such as those disclosed in the cited documents, have been in existence for many years. This is evidenced by the cited documents themselves: the priority date of Shorey is in 1979, almost 20 years before the priority date of the present application, and Gunnell was filed in 1900.

Despite the long-felt need for an improved fastening mechanism and the long existence of cable grips in the hardware field, such as those described in the cited documents, there is no evidence that any medical practitioner has ever considered adapting a cable grip of the type of

the cited art for use as a medical fastener in the manner claimed. Therefore, any assertion that Shorey or Gunnell could be adapted to provide the medical fastener claimed can only be based on **improper hindsight reasoning**.

Therefore, in summary, it is respectfully submitted that Claim 81 is nonobvious over Shorey alone or in combination with Gunnell, and the Examiner is respectfully requested to confirm that Claim 81 is allowable.

2. Claim 81 Is Not Obvious In View of Favalora and/or Kellems

Previous Claim 69, on which Claim 81 is based, was rejected under 35 U.S.C. §103 based on Favalora in view of Kellems in the Office Action of June 5, 2006. Therefore, it seems appropriate to comment on this rejection with respect to the newly-presented claims.

The Examiner recognizes in the Office Action of June 5, 2006, that Favalora “does not teach a medical or surgical fastener.” The Examiner further recognizes that Favalora “does not teach a second aperture through which the tube can pass at a second end of the sleeve.”

It is further submitted that Favalora nowhere discloses a fastener comprising a “sterile tubular sleeve.” Therefore, the claimed fastener is distinct from the device described in Favalora in multiple, different ways.

For at least the same reasons as set out above in relation to Shorey, it would not be obvious for a person of ordinary skill in the art to develop the claimed fastener based on Favalora, either alone or in combination with Kellems. Neither document teaches or suggests any use of the devices described except for as cable grips in the field of hardware tools. Therefore, it **would not be obvious to provide a sterile tubular sleeve** as claimed.

Therefore, in summary, it is respectfully submitted that Claim 81 is nonobvious over Favalora alone or in combination with Kellems.

3. Claim 95 Is Not Obvious In View of Shorey and/or Gunnell

The non-obvious nature of Claim 95 will be discussed below with reference to factual inquiries stated in *Graham v. John Deere Co.* 383 U.S. 1, 148 USPQ 459 (1966), among other analysis.

a. *Determining the scope and content of the prior art*

The Examiner has rejected the previous claims of the application under 35 U.S.C. §103(a) as being unpatentable over Shorey in view of Gunnell.

*b. Differences between the claimed invention and the prior art*

As recognized by the Examiner and noted above, Shorey discloses a “cable grip” for fitting over a cable. Gunnell discloses a connector for a hose. Neither Shorey nor Gunnell disclose “a medical or surgical fastener.” Indeed, neither Shorey nor Gunnell teach or suggest the use of the cable grip and hose connector described in any field other than hardware.

It is further clear that Shorey nowhere discloses a tubular sleeve having “a ring at at least one end of the sleeve, the ring surrounding the first aperture or the second aperture and the ring being operable to shorten the length of the sleeve.” Instead, the grip described in Shorey ends at one end with “cable loops, or eyes, 48” and at the other end with a woven mesh. Similarly, Gunnell does not disclose providing a ring operable to shorten the length of the sleeve. In fact, the alleged “sleeve” in Gunnell is simply a protective lacing, for protecting and covering the hose, which is arranged to be trapped between components A and B in the connector. Gunnell discloses that the lacing is not necessary to the invention (Page 2 Lines 68-72) and it is certainly not disclosed with any ring that is “operable to shorten the length of the sleeve.” Hence, there is clearly a gap between the cited art and the claimed invention. The cited art does not fill this gap, nor is the invention rendered obvious by any other means.

*c. Resolving the level of ordinary skill in the art*

As set out above, since the claimed fastener is a medical or surgical fastener, it is respectfully submitted that a person of ordinary skill in the pertinent art would have been a medical practitioner, such as a doctor. Such a person would have been aware of the previous mechanisms for securing a tube to a patient, such as the adhesive tape bridges and other devices disclosed on Pages 2-7 of the present application.

*d. Teaching / Suggestion / Motivation test*

The cited art does not teach, suggest, or motivate the present invention. As stated above, the TSM test remains “the primary guarantor” against hindsight analysis, which appears to be present in the current Office Action.

It is clear from the discussion above that the provision of a medical or surgical fastener comprising a tubular sleeve having a ring at at least one end of the sleeve surrounding the first aperture or the second aperture and operable to shorten the length of the sleeve is nowhere taught in the cited art. Therefore, it is **simply not possible to combine elements** from the cited

documents, or to substitute one element with an element from another document **to arrive at the claimed fastener.**

There is no teaching or suggestion in the cited art that providing a ring to enable shortening and lengthening of the sleeve may be advantageous.

In relation to the collar previously claimed as part of Claim 80, the Examiner refers to the “terminations 44, 46” from which the cable loops extend in Shorey. However, these terminations are not relevant to the amended claims, since they do not surround the first aperture at one end of the tubular sleeve nor the second aperture at the other end of the tubular sleeve. Instead they are simply attached to parts of the cable grip, forming the cable loops. Further, the terminations are not operable to shorten the length of the cable grip: pushing the terminations towards the cable grip would simply bend the portions of the cable grip immediately below and would not shorten the length of the tubular portion of the cable grip surrounding the wire.

It is not clear how a skilled person could adapt Shorey to provide a ring surrounding the first or second aperture and operable to shorten the length of the sleeve. In fact, providing such a ring in Shorey would render this device **unsatisfactory for its intended purpose**. The intended purpose of Shorey is to enable a cable grip to expand over an enlarged portion of a cable (for example over a cable connector). This is achieved by ensuring that the tubular sleeve portion of the cable grip, 42c, is located in a middle portion of the braided grip. As illustrated in Fig. 3, on either side of the tubular portion, the braiding continues; at one end into an open, split portion, to point 42a and at the other end into tubular metal sleeves from which the cable loops, 48 extend. In providing a tubular portion only in the middle of the cable grip, this enables the tubular portion to expand further and fit over larger discontinuities in the cable. This is explained on Page 2 Lines 116-129, “if the grip 40 were tubular to the end 40a the maximum diameter of a cable 50, or a relatively large diameter discontinuity (not shown), in the cable acceptable by the grip 40 would be limited by the maximum diameter to which the end 42a could be expanded. However, by leaving open the end of grip 40 between the positions 42c and 42a, it has been found that the diameter of the tubular part at position 42 can be increased quite considerably to accept the usual relatively large diameter discontinuity such as a plug and socket so that the grip can be pushed over the discontinuity and cable to the required position.”

Therefore, if Shorey was modified to add a ring around the aperture at either end of the tubular portion of the cable grip, such a ring would not allow the cable grip to expand in the



manner claimed to fit over larger discontinuities. This would render the cable grip of Shorey unsatisfactory for its intended purpose of fitting the cable grip over larger discontinuities. Therefore, a skilled person simply **would not make this change** to the cable grip described in Shorey.

The provision of a ring around the laced hose protector in Kellems would not be necessary. The lacing is instead “crowded backward” as the hose is inserted into member A. Further, the provision of a ring around the lacing in Kellems may also render the system described in Kellems **unsatisfactory for its intended purpose**, since a ring is likely to prevent the lacing from stretching over the tapered exterior of member A and being effectively confined between member A and member B.

Therefore, in summary, it is respectfully submitted that Claim 95 is nonobvious over Shorey alone or in combination with Gunnell, and the Examiner is respectfully requested to confirm that Claim 95 is allowable.

4. Claim 95 Is Not Obvious In View of Favalora and/or Kellems

None of the claims pending when the Office Action of June 5, 2006, issued included the feature of a ring surrounding the first aperture or the second aperture and operable to shorten the length of the sleeve. Furthermore, the Examiner considered previous Claim 80, which included the feature of a collar operable to vary the length of the sleeve, to be allowable over these documents. Therefore, the applicant respectfully submits that new Claim 95 is also allowable over these documents. However, for completeness, Applicant will comment briefly on these documents in relation to new Claim 95.

As noted above, neither Favalora nor Kellems discloses a medical or surgical fastener for securing a tube to a patient. Therefore, Claim 95 is novel and non-obvious over these documents at least for reasons corresponding to those set out above for Claim 81.

Further, neither document discloses a ring surrounding the first aperture or the second aperture and operable to shorten the length of the sleeve.

Favalora discloses a “ring or pulling member 14,” which is attached to the closed end of the pulling tool. However, this pulling member does not surround an aperture of the pulling tool, since the sleeve is closed at that end of the tool. Further, the pulling member may cause the length of the tool to be increased, but it is not operable to shorten the length of the sleeve. Therefore, Claim 95 is further novel and non-obvious over Favalora.

It is difficult to identify which feature in Kellems might be equated to the claimed “ring,” but it is clear that there is no ring-like component in Kellems that surrounds an aperture, since Kellems also discloses a closed-end structure. Further the “collars” described in Kellems are not disclosed as being operable to shorten the length of the sleeve. Therefore, Claim 95 is further novel and non-obvious over Kellems.

5. The Dependent Claims Are Allowable

The dependent claims are novel and nonobvious at least by virtue of their dependency on Claims 81 and 95. However, for the avoidance of doubt, it is noted that the dependent claims are believed to add further novel and non-obvious features.

6. The Claims Are Nonobvious In View of Declarations

Even after the Supreme Court’s *KSR* decision, prior art must still be analyzed to determine if it is analogous. *In re Icon Health and Fitness, Inc.*, 496 F.3d 1374, 1379-1380 (Fed. Cir. 2007) (stating that a reference may serve as analogous art “**if reasonable pertinent to the problem addressed**” by an application and noting that “a reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, **logically would have commended itself to an inventor’s attention in considering his problem.**”) (emphasis added).

Here, the primary cited art document—Shorey—represents impermissible nonanalogous art. For this independent reason, the present rejections are not supported, and Applicant respectfully requests that they be withdrawn so that this application may issue.

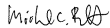
The Examiner is invited to review the declarations of Marc Howard Spinoza and Martin John Elliott, which have been filed concurrently with this response. These declarations support the nonobviousness of the present invention and particularly, the nonanalogous nature of the Shorey reference. *See* Spinoza Declaration, ¶¶ 7-9; Elliott Declaration, ¶¶ 15-17. Additionally, the Elliott Declaration sets forth additional evidence of nonobviousness, including pertinent secondary considerations that expand upon the concepts argued in this response. *See, e.g.*, Elliott Declaration, ¶¶ 7-11. Both Spinoza and Elliott disagree with the Examiner’s assertion that a “tube is analogous in structure to a cable line” and that it “would have been obvious to one of ordinary skill in the art to recognize that the cable line and the tube are interchangeable and can be used in medical arts as it relates with the tube.” *See* Elliott Declaration, ¶ 14; Spinoza Declaration, ¶ 5.

Based on this additional evidence of nonobviousness, Applicant respectfully requests all rejections be withdrawn. The present claims are believed to be allowable.

**Conclusion**

Applicant believes that these remarks fully respond to all outstanding matters for this application. Applicant respectfully requests that the rejections of all claims be withdrawn so the claims can issue. If the Examiner has any questions, please contact the undersigned attorney at 512-536-3018.

Respectfully submitted,



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Date: April 17, 2008